



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-N-4849]

### Agency Information Collection Activities; Proposed Collection; Comment Request; Food Allergen Labeling and Reporting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with statutory provisions applicable to ingredients derived from major food allergens.

**DATES:** Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2023-N-4849 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Food Allergen Labeling and Reporting." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential

Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:  
<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on the following topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Food Allergen Labeling and Reporting

OMB Control Number 0910-0792--Revision

This information collection helps support implementation of statutory requirements pertaining to ingredients derived from major food allergens. The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines the term “major food allergen” (section 201(qq) of the FD&C Act (21 U.S.C. 321(qq))) and provides that foods are misbranded unless they declare the presence of each major food allergen on the product label using the name of the food source from which the major food allergen is derived or are exempt from the requirement. Under

sections 403(w)(6) and (7) of the FD&C Act (21 U.S.C. 343(w)(6) and (7)), respondents may request an FDA determination that an ingredient is exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. Alternatively, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient “does not contain allergenic protein” or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act (21 U.S.C. 348) that the ingredient “does not cause an allergic response that poses a risk to human health” (section 403(w)(7) of the FD&C Act).

To assist respondents with the information collection in this regard, the document entitled “Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications” (June 2015), available on our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-allergen-labeling-exemption-petitions-and-notifications>, communicates information we recommend respondents include in petitions submitted under sections 403(w)(6) and (7) of the FD&C Act or notifications submitted under section 409 of the FD&C Act. We use the information submitted in the petition or notification to determine whether the ingredient satisfies the criteria of section 403(w)(6) and (7) of the FD&C Act for granting the exemption. The allergen information disclosed on the label or labeling of a food product benefits consumers who purchase that food product. Because even small exposure to a food allergen can potentially cause an adverse reaction, consumers rely upon food labeling information to help determine their product choices.

On April 23, 2021, the definition of the term *major food allergen* was amended by the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act) (Pub. L. 117-11) to include sesame. Accordingly, we are revising the information collection to account for burden attributable to required declarations and/or associated requests for exemption as they pertain to foods that include sesame. We issued the draft guidance document entitled “Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of

the Federal Food, Drug, and Cosmetic Act (Edition 5)” (November 2022), available on our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5>, that once finalized, will communicate our current thinking regarding the labeling of food allergens, including sesame in food products regulated under section 403 of the FD&C Act. The guidance was issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

*Description of Respondents:* The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States subject to the labeling requirements and prohibitions found in section 403 of the FD&C Act.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

FD&C Act Section; Information Collection Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours	Total Capital Costs
403; review product labeling for compliance with applicable statutory requirements.	77,500	1	77,500	1	77,500	0
403; redesign/modifications to product labeling for compliance with applicable statutory requirements	775	1	775	16	12,400	\$1,414,375
Total					89,900	\$1,414,375

<sup>1</sup> There are no operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Reporting Burden<sup>1</sup>

FD&C Act Section; Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
403(w)(6); petition for exemptions	6	1	6	100	600
403(w)(7); notification submissions	6	1	6	68	408
Total					1,008

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate of the third-party disclosure burden associated with food allergen labeling under section 403(w)(1) of the FD&C Act includes the time we assume respondents need to review the labels of new or reformulated products for compliance with the requirements of

section 403(w)(1) of the FD&C Act, along with the time needed to make any needed modifications to the labels of those products. We believe firms have already redesigned their labels to comply with requirements under the Food Allergen Labeling and Consumer Protection Act of 2004. However, this estimate accounts for firms that will redesign their label to comply with requirements under the FASTER Act. Our estimated reporting burden is based on our past experience with these submissions. We have increased our cumulative estimate by 12,552 hours and 776 responses annually to reflect the inclusion of sesame as a major food allergen.

Dated: December 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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